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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,463	08/04/2003	Robert W. Brueggemeier	22727/04124	6736
24024	7590	01/19/2006	EXAMINER	
CALFEE HALTER & GRISWOLD, LLP			CHANG, CELIA C	
800 SUPERIOR AVENUE			ART UNIT	
SUITE 1400			PAPER NUMBER	
CLEVELAND, OH 44114			1625	

DATE MAILED: 01/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/634,463

Applicant(s)

BRUEGGEMEIER ET AL.

Examiner

Celia Chang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2005.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1 and 20 is/are rejected.
7) ☒ Claim(s) 2-19, 21 and 22 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Amendment and response filed by applicants dated Oct. 31, 2005. Claim 23 has been canceled. Claims 1-22 are pending. Prosecution continues with respect to the elected scope wherein R3 is OCH₂CH₂-1-piperidine.
2. Applicants affirmed the election and reserved the right to prosecute nonelected compounds in divisional applications. However, the nonelected compounds have not been canceled from the claims. It is recommended that the remaining subject matter be deleted from the claims.
3. The rejection of claims 1-23 under 35 USC 102(f) is dropped in view of the Declaration filed by Brueggemeier under Rule 1.132.
4. The rejection of claim 1 under 35 USC 103(a) over Chiesi et al. '403 in view of King is maintained for reason of record.

Applicants argument based on bioisosteric replacement is unpredictable does not obviate the rejection. Please note that the suggestion and reasonable expectation of success are both clearly disclosed by the King reference. Not only the suggestion that modification is rational it is also stated that depending on the activity in binding sites (see p.209), bioisosterism is "expected" to produce similar activity compounds with variation of activity. In establishing a prima facie obviousness case, the suggestion does not have to be absolutely predictable, only a reasonable expectation of success (see Ex parte Erlich 3 USPQ2d 1011). As it was clearly disclosed on page 209 of King, a reasonable expectation of success is the rational for suggesting modification to obtain "more" active compounds as "drug" design.

To obviate an established prima facie case, unexpectancy must be demonstrated with factual evidence not mere argument.

5. The rejection of claims 20-21 under 35 USC 112 first paragraph is maintained for reason of record against claim 20.

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The limitation of claim 21 to treating breast cancer obviated the rejection for claim 21 but such limitation has not been found in claim 20, thus, the rejection is maintained.

6. The rejection of claim 23 is moot in view of the cancellation of the claim.

Claims 2-19, 21-22 are objected to as being dependent upon a rejected base claim, but would be allowable upon deletion of the nonelected subject matter and rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Jan. 17, 2005



Celia Chang
Primary Examiner
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